

Remarks

Claims 1-14 are amended. No new matter was added by way of amendment. Claims 1-14 are pending.

Applicant has reviewed the Restriction Requirement mailed May 31, 2007 and provisionally elects, with traverse, the claims of Group I (claims 1-14). Reconsideration and withdrawal of the Restriction Requirement, in view of the remarks presented herein, is respectfully requested.

Applicant notes that the Examiner has placed all of the pending claims (claims 1-14) in a single group (Group I), and thus, Applicant has elected Group I. Applicant further notes that all of the claims have been amended to method claims reciting the administration of the adjuvant composition, and thus, all the method claims also belong in one Group (Group I).

The Examiner has stated that “the inventions listed as Group I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features....” Specifically, the Examiner states that the special technical feature of Group I is an adjuvant composition and that this technical feature is anticipated by Cox et al. WO 96/11711. However, Applicant respectfully disagrees.

According to Rule 13.2 PCT, the requirement of unity of invention contained in Rule 13.1 PCT is fulfilled “when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features...that define the contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”

Applicant respectfully submits that the instant claims are technically related in that they relate to administration of an adjuvant composition in which fraction A of Quil A could be integrated alone in an iscom or iscom matrix particle and that at least one other adjuvant could be in free form or could be integrated in another different iscom particle or iscom matrix particle and mixed with the iscom or iscom matrix particle having fraction A of Quil A integrated therein. Applicant respectfully submits that this feature is novel and unobvious and forms a single general inventive concept. The following arguments will more clearly illustrate this concept. Thus, Applicant respectfully submits that there is no lack of unity present in the application. Therefore, Applicant respectfully requests the withdrawal of the lack of unity rejection.

The Examiner states that the technical feature of Group I is anticipated by Cox et al. (WO 96/11711).

Cox et al. generally relate to a saponin preparation comprising saponins of Quillaja saponaria, said preparation comprising from 50% to 90% by weight of fraction A of Quil A and from 50% to 10% by weight of fraction C.

According to claim 4 of Cox et al., the saponin preparation may be used in the form of an immunostimulatory complex (iscom) matrix, comprising a saponin preparation according to any of claims 1 to 3, a sterol and optionally a lipid. Thus, both fraction A and C of Quil A are integrated in the same complex. Cox et al. does not disclose that fraction A and fraction C are in physically different iscom matrix complexes or that fraction C is in free form.

Furthermore, Cox et al. do not disclose that fraction A of Quil A could be integrated alone in an iscom or iscom matrix particle and that fraction C could be free or that fraction C could be integrated in another different iscom particle or iscom matrix particle and mixed with the iscom or iscom matrix particle having fraction A of Quil A integrated therein. Cox et al. must comprise fraction A of Quil A and fraction C from Quil A in the same iscom particles or iscom matrix particles when iscoms are used.

The instant invention relates to a composition that is not described in the Cox et al. document. Thus, the claims are novel in view of the cited documents and provide a single general inventive concept, namely that fraction A of Quil A could be integrated alone in an iscom or iscom matrix particle and that at least one other adjuvant could be in free form or could be integrated in another different iscom particle or iscom matrix particle and mixed with the iscom or iscom matrix particle having fraction A of Quil A integrated therein. Thus, it is respectfully submitted that the reason put forth for non-unity based on Cox et al. is not proper. Hence, Applicant respectfully requests the withdrawal of the lack of unity rejection and that the claims be considered as one group.

The Examiner refers to page 3, lines 20-30, and pages 4-5 of Cox et al. The second paragraph on page 4 of Cox et al. discloses that "[t]he saponin preparation may, if desired, include minor amounts (for example up to 40% by weight) of other adjuvant materials with desired immunostimulatory properties, including minor amounts of Fraction B of Quil A or of

other saponins.” Thus, the saponin preparation of Cox et al. may comprise up to 40% of other adjuvants, but the figure of 40% does not relate to a final composition that may comprise an iscom complex or iscom matrix complex.

In the Office Action mailed May 31, 2007, the Examiner also required an election of species for search purposes if the Applicant elects Group I (Applicant respectfully notes that there is only one Group to elect; namely, Group I). Applicant notes that upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141.

For the sake of clarity, Applicant notes that the instant claims recite “fraction A of Quil A together with at least one other adjuvant.” Applicant believes that the species election is directed to “at least one other adjuvant,” as “fraction A of Quil A” is a required element of claim 1 as currently pending. If this is incorrect, Applicant respectfully requests clarification of the election of species requirement in the next Official Action and that Applicant be given the opportunity to modify Applicant’s response.

With the above understanding in mind, in response to the election of species requirement (i.e., “at least one other adjuvant”), Applicant elects for Species 1 – adjuvant: L) Monophosphoryl lipid A and for Species 2 – saponin fraction: B) Fraction B, with traverse, as the species for search purposes. The species election is traversed in that the claims, and species, provide a single general inventive concept, that fraction A of Quil A could be integrated alone in an iscom or iscom matrix particle and that at least one other adjuvant could be in free form or could be integrated in another different iscom particle or iscom matrix particle and mixed with the iscom or iscom matrix particle having fraction A of Quil A integrated therein. Thus, Applicant respectfully requests withdrawal of the species election. Applicant believes that claims 1-14 read on the elected species.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully Submitted,

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CERTIFICATE UNDER 37 CFR § 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelop addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 30TH day of August 2007.

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